GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINSITRATION

L.Dis.No.6436/BM/2013 **Dated: 31-04-2014**

From:

P.Nagabhushanam, M.Pharm, BL, MBA
Director & Licensing Authority
O/o.the Director General,
Drugs and Copyright.
Drugs Control Administration,
Vengalraonagar,Hyderabad – 500 038.

To

M/s.Symed Labs Limited,
Plot No.25/B,
Phase-III, I.D.A.,
Jeedimetla
Hyderabad-500055.

Sirs,

Sub:- Drugs and Cosmetics Act,1940 and Rules made thereunder – Renewal of Drug Licence in Form-25 for the period from 28-05-2013 to 27-05-2018- Regarding.

Ref:- Your application dt.22-04-2013

With reference to your application cited, I forward herewith the Drug manufacturing **Licence in Form-25 bearing No.26/RR/AP/2003/B/R dt.28-05-2003** duly renewed for the periods from 28-05-2013 to 27-05-2018, for manufacture of the products mentioned in the list enclosed

The above Licence is renewed subject to the following conditions:

1. You are informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.

2. The provision of Drugs Price Control Order, 2013 shall be complied with.

3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, color combination etc., and shall comply with all the provisions relating to the labeling of Drugs.

4. Specific permission for each export order need not be obtained. However, the details of exports by the exporter shall be furnished immediately after completion of each export in the format mentioned below.

Sl. No.	Date of export.	Names of the drugs exported	Batch No. of the drug.	Quantity of the drug.	Name of the importing country.
1.	2.	3.	4.	5.	6.

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

31/5/14

5. Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.

6. The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.

7. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.

8. While the permissions for export of drugs earlier granted still hold good, the conditions attached for such permissions stand amended as mentioned above

In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19th The Mal Morar, Gwalior-6 so far as the provisions of the NDPS Act and the Rules are concerned in the matter.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licences/permissions issued herewith are liable for suspension/cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

Yours faithfully,

31/5/14

DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION

L.Dis.No.6436/BM/2013 Renewal of Drug Licence to M/s.Symed Labs Limited,Plot No.25/B, Phase-III, I.D.A., Jeedimetla,Hyderabad-500055. in Form-25 bearing No.26/RR/AP/2003/B/R dt.28-05-2003 valid up to 27-05-2018

1. FLUCONAZOLE	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
2. KETORLAC TROMETHAMINE	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
3. CIPROFLOXACIN	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
4. CETIRIZINE DI HYDROCHLORIDE	IP / USP /Ph.Eur / BP	For DOMESTIC & EXPORT
5. TIZANIDINE HYDROCHLORIDE	IP / USP	For DOMESTIC & EXPORT
6. MOSAPRIDE CITRATE DIHYDRATE	IP / IH	For DOMESTIC & EXPORT
7. LINEZOLID	IP / IH	For DOMESTIC & EXPORT
8. TOPIRAMATE	IP / USP	For DOMESTIC & EXPORT
9. ZALEPLON	IH / USP	For DOMESTIC & EXPORT
10. TAMSULOSINE HYDROCHLORIDE	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
11. LEVOCETIRIZINE DIHYDROCHLORIDE	IP / IH	For DOMESTIC & EXPORT
12. HYDROXYZINE DIHYDROCHLORIDE	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
13. THALIDOMIDE	USP	For DOMESTIC & EXPORT
14. ITOPRIDE HYDROCHLORIDE	IH	For DOMESTIC & EXPORT
15. BRIMONIDINE TARTARATE	IH	For DOMESTIC & EXPORT
16. RACECADOTRIL	IP / Ph.Eur / BP	For DOMESTIC & EXPORT
17. CARVEDILOL	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
18. IRON SUCROSE	IH	For DOMESTIC & EXPORT
19. GEMFIBROZIL	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
20. ONDANSETRON HCL DI-HYDRATE	IP / USP / Ph.Eur / BP	For DOMESTIC & EXPORT
21. PREGABALIN	IH / IP	For DOMESTIC & EXPORT
22. AMISULPRIDE	IP / Ph.Eur / IH / BP	For DOMESTIC & EXPORT
23. LEVOSULPIRIDE	IH	For DOMESTIC & EXPORT
24. EPALRESTAT	IH	For DOMESTIC & EXPORT
25. CINITAPRIDE HYDROGEN TARTRATE	IH	For DOMESTIC & EXPORT
26. ESZOPICLONE	USP / Ph.Eur	For DOMESTIC & EXPORT
27. LANTHANUM CARBONATE	IH	For DOMESTIC & EXPORT
28. PALIPERIDONE	IH	For DOMESTIC & EXPORT
29. ZOTEPINE	IH	For DOMESTIC & EXPORT
30. MECLIZINE HCl	USP / IP / Ph.Eur / BP	For DOMESTIC & EXPORT
31. DEFERASIROX	IH	For DOMESTIC & EXPORT
32. DAPOXETINE HCl	IP / IH	For DOMESTIC & EXPORT
33. CARVIDILOL PHOSPHATE	IH	For DOMESTIC & EXPORT
34. TAPENTADOL HYDROCHLORIDE	IP / IH	For DOMESTIC & EXPORT
35. DRONEDARONE HYDROCHLORIDE	IH	For DOMESTIC & EXPORT
36. ILOPERIDONE	IP / IH	For DOMESTIC & EXPORT
37. ASENAPINE MALEATE	IP / IH	For DOMESTIC & EXPORT
38. NAFTOPIDIL	IH	For DOMESTIC & EXPORT

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION

31/5/19

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINSITRATION

L.Dis.No.6436/BM/2013 **Dated: 31-05-2014**

From:

P.Nagabhushanam, M.Pharm, BL, MBA
Director & Licensing Authority
O/o.the Director General,
Drugs and Copyright.
Drugs Control Administration,
Vengalraonagar,Hyderabad – 500 038.

To

M/s.Symed Labs Limited,
Plot No.25/B,
Phase-III, I.D.A.,
Jeedimetla
Hyderabad-500055.

Sirs,

Sub:- Drugs and Cosmetics Act,1940 and Rules made thereunder – Renewal of Drug Licence in Form-25 for the period from 28-05-2013 to 27-05-2018- Regarding.

Ref:- 1.Your application dt.05-04-2013
2. This office L.Dis.No.11825/B2M/2008 dt.28-03-2009
3. This office L.Dis.No.2308/BM/2011 dt.24-03-2011
4. This office L.Dis.No.6171/BM/2012 dt.25-06-2012
5.This office L.Dis.No.16988/BM/2012 dt.04-01-2013

With reference to your application cited, I forward herewith the Drug manufacturing **Licence in Form-25 bearing No.26/RR/AP/2003/B/R dt.28-05-2003** duly renewed for the periods from 28-05-2013 to 27-05-2018, for manufacture of the following products of the specific quantity mentioned and to be exported to the country specified.

1. PHENTERMINE HYDROCHLORIDE USP 200 Kgs (For Export to Canada)
   4800 Kgs (For Export to USA)
   400 Kgs (For Export to Germany)
   100 Kgs (For Export to Korea)
   100 Kgs (For Export to Argentina)
   50 Kgs (For Export to Brazil
   100 Kgs (For Export to Mexico)
   50 Kgs (For Export to Turkey)
2. PHENTERMINE BASE USP 1000 Kgs (For Export to Canada)
3. CARBINOXAMINE MALEATE USP 300 Kgs (For Export to Germany)
   200 Kgs (For Export to USA)
4. SIBUTRAMINE HYDROCHLORIDE USP 1000 Kgs (For Export to Russia)

The above Licence is renewed subject to the following conditions:

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

31/5/14

L.Dis.No.6436/BM/2013 Renewal of Drug Licence to M/s.Symed Labs Limited,Plot No.25/B, Phase-III, I.D.A., Jeedimetla,Hyderabad-500055. in Form-25 bearing No.26/RR/AP/2003/B/R dt.28-05-2003 valid up to 27-05-2018

1. The batch to be exported shall undergo quality control testing at your Laboratory or at the destined site.
2. You are required to ensure that the quantity of the drug(s) manufactured on the basis of the above "NOC" is exported and no part of it is diverted for domestic sale in India, through a declaration in the form of an affidavit on Non-Judicial Stamp paper.
3. You are requested to submit the information pertaining to quantities of drugs manufactured and exported to the state licensing Authority and Zonal/Sub Zonal of CDSCO after completion of the export under this approval..
4. You shall ensured that the drug(s) manufactured on the basis of NOC given as per your export order its exported and that no part of it is diverted for domestic sale in India.
5. In the even of the relevant Export order being cancelled, you shall ensure physical destruction of all unexported quantity of the drugs and shall submit a declaration Dy.Drugs Controller (I) and State Licensing Authority in the form of an affidavit on a non –judicial Stamp paper.
6. You shall make available for inspection of the appropriate authorities on completion of the export orders and furnish information to this office regarding the actual quantities of the drug(s) produced, details regarding each consignment dispatched, remaining stocks of the drug and related raw materials and intermediates in hand.
7. You shall ensure that the drug for which "NOC" has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.
8. Detailed particulars of rejects/ returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.
9. The specification/standards asked for by the Importing Country/firm shall be complied with while exporting the drugs.
10. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.You are informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.

Further, you are informed that non-compliance of any of the conditions mentioned above the matter will be reviewed and the licences/permissions issued herewith are liable for suspension/cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

Yours faithfully,

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH HYDERABAD

DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION
31/5/14